

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|----------------|---|---|-------------------|------|
| Appl. No.      | : | 10/634,642  | Confirmation No.: | 7193 |
| Applicant      | : | William Suttle Peters, et al.                                 |                   |      |
| Filing Date    | : | August 4, 2003  |                   |      |
| Title          | : | Intraluminal Inflatable Counter-Pulsation Heart Assist Device |                   |      |
| Group Art Unit | : | 3762  |                   |      |
| Examiner       | : | Alyssa M. Alter   |                   |      |
| Docket No.     | : | 13634.4003  |                   |      |
| Customer No.   | : | 34313   |                   |      |

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**REPLY BRIEF**

Sir:

In reply to the Examiner's Answer dated November 12, 2009, Applicant files a Reply Brief in accordance with 37 CFR §§ 41.41 and 41.37(c).

***Real Party in Interest***

Sunshine Heart Company Pty Ltd of Australia is the real party in interest.

***Related Appeals and Interferences***

There are no known related appeals or interferences.

***Status of Claims***

Claims 1-17 and 19-32 are pending in this application. These claims have all been rejected and are the claims on appeal. Claim 18 has been cancelled.

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### ***Status of Amendments***

An Amendment filed on September 28, 2006 has been entered for the purpose of appeal and overcomes the rejections based on 35 U.S.C. 112, first and second paragraphs made in the final rejection dated August 18, 2006.

### ***Summary of Claimed Subject Matter***

There are three independent claims, which are apparatus claims 1 and 30, and claim 23, a method claim. Reference to the drawings are shown in parentheses

Claim 1 is directed to a heart assist device (10) which can be placed in a blood vessel such as an artery (22) and comprises an inflatable member (14) which can be alternately inflated and deflated to create a pumping action to assist the pumping action of the heart. The device comprises a balloon (14) which can be moved between an inflated condition and a deflated condition and a shell (12) to which the balloon is attached. The shell is adapted to hold the device in place inside a blood vessel and adjacent to an inside surface of the blood vessel. In its deflated condition, the balloon lies closely adjacent to the wall of the shell and in the inflated condition, the balloon projects into the vessel from the wall.

Claim 30 is directed to a heart assisted device (10) comprising an intraluminal inflatable balloon (14) which is attached to a shell (12) which is adapted to be located adjacent to the surface of an inner wall of an arterial vessel, the shell (12) having an arcuate cross section (as shown in Figure 2) the interior surface of balloon (14) facing the concave surface of the shell and the shell having a port (18) in its wall to permit fluid flow in a direction transverse to the direction of the flow of blood through the vessel and the port being connected to a tube (30).

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The apparatus of claim 1 is described in the specification at page 4, line 27 - page 5, line 10. Claim 30 is described at page 1, line 27 - page 5, line 10, page 5, lines 26-30 and at page 6, lines 1-6.

Method claim 23 comprises placing the heart assist device (10) against the inner surface of the wall of a blood vessel, connecting the inflatable balloon (14) to a fluid pressure source (26), and energizing the fluid pressure source to expand and contract the balloon which such expansion and contraction being in counter-pulsation with the heart of the patient. The method of claim 23 is described at page 3, lines 26-32, and page 4, line 27 - page 5, line 10.

The device is best shown in Figures 1 and 4, wherein the shell is denoted by numeral 12 and the balloon by numeral 14. The device and its operation are described at pages 4-6 of the specification.

### ***Grounds of Rejection To Be Reviewed on Appeal***

#### ***New Grounds of Rejection***

Claims 1-11, 13-14, 16-17, 23-26 and 28-31 have been rejected as anticipated by Dobak Patent No. 5,827,171 under Section 102. Claims 1-17, 23-26 and 28-31 stand rejected as anticipated by Dobak Patent No. 5,820,542 under Section 102. Claims 21, 22 and 27 have been rejected as unpatentable over Dobak Patent No. 5,827,171 or Dobak Patent No. 5,820,542 under Section 103. Claims 19 and 20 have been rejected as unpatentable under Section 103 over Dobak Patent No. 5,827,171 or Dobak Patent No. 5,820,542 in view of Lederman Patent No. 6,210,318. Claims 14 and 32 have been rejected as unpatentable under Section 103 over Dobak Patent No. 5,827,171 or Dobak Patent No. 5,820,542.

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***Reason Why This Appeal Should Be Remanded To The Examiner For Consideration Of Additional Prior Art***

As stated in Applicant's Information Disclosure Statement filed on October 27, 2006, Applicant believes Freed Patent No. 6,471,633 to be more pertinent to the claimed invention than any of the prior art relied upon by the Examiner. In that Information Disclosure Statement, Applicant stated:

Applicant requests that the final rejection currently in effect in the present application be vacated and that the prosecution proceed on the basis of the Freed patent.

This request has gone unheeded and is believed to create a situation in which it would be a waste of time for this appeal to go forward. However, this situation can be remedied by a remand of this application to the Examiner for the purpose of considering the Freed patent and such remand is respectfully requested.

**Introduction**

Before responding to the arguments made by the Examiner in the Examiner's Answer, Applicant wishes to correct an error which appears at page 6, lines 7 and 8 of Applicant's Amended Appeal Brief filed 6/26/09 wherein Applicant states that "claim 1 has also been amended to recite that the shell is non-expandable." Such an amendment was made, but was subsequently deleted.

However, as will be explained in more detail below, this recitation simply recited an inherent property (non-expandability) of the "shell" recited in the claims. In other words, the plain meaning

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of the recitation “shell” is that it is non-expandable and the deletion of the word “non-expandable” simply removed a term which recited an inherent property and was thus redundant.

### **Argument**

#### **The Meaning of “Shell”**

The plain meaning of the word “shell” is, as stated in the first two definitional statements for this word in *Random House Webster’s College Dictionary* (1991), as follows:

shell – “1. a hard outer coating of an animal as of a clam, snail, lobster or turtle. 2. the material constituting any of various coverings of this kind.”

In light of the foregoing definition, it is plain that the “shell” recited in the appealed claims must be construed to be a “hard outer covering” which, of course, by its very nature cannot be expandable. The Examiner, however, argues at page 13, lines 1-2 (second paragraph under heading “Response to Argument”) that:

“...the Examiner considers the outer balloon 18 (of Dobak Patents Nos. 5,827,171 and 5,820,542) to function as a shell.”

The Examiner’s position in this regard is diametrically opposite to proper usage of the English language.

All of the appealed claims are limited to a device comprising a “shell” or the use of a device comprising a “shell”. Contrary to the Examiner’s assertion, neither of the Dobak references relied upon contains any disclosure or suggestion of the use of a device comprising a shell. The Examiner’s reliance on “outer balloon 18” of the Dobak patents as a shell is particularly misplaced. As shown in Figure 1 of each of the Dobak patents and as disclosed at column 8, lines 39-46 of

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Dobak '542, the purpose of outer balloon 18 is to create a pressure chamber which can be used to compress the expansion member 20 in balloon 16 so that the size of the device can be reduced for the purpose of removing it from the vasculature of a patient. Nothing could be further removed from the "inelastic, preferably plastic shell 12" disclosed in paragraph 27 of the present application and such shell is recited in all of the appealed claims.

The present device also includes a membrane 14 which, as disclosed in paragraph 27, is "sealingly attached to periphery of the shell 12." This is what is recited in claim 1 of the present application. As disclosed in paragraph 29 of the present application, the device can **also** comprise a stent and this is recited in claim 2. Thus, in Applicant's device, the shell is not a stent and the stent is not a shell. In marked contrast, the devices of Dobak consist of multiple essentially concentric balloons as shown in Figure 1 (3 balloons) and Figure 2 (2 balloons), one of which may have a stent encased in it. The further embodiments shown in Figures 3-18 of Dobak '542 and 3-13 of Dobak '171 which make use of helical springs, various types of self-expanding stents, etc. are far removed from the subject matter of the present application. These other embodiments all have one thing in common with the embodiments shown in Figures 1 and 2, namely, all of them have mechanisms such as prongs or coils, designed to permit compression of an expandable device to remove it from the vasculature. Thus, each of these devices is delivered in a compressed configuration, caused to expand by expanding a balloon or by the use of a self-expanding mechanism and then compressed to accomplish removal from the vasculature. As such, they are fundamentally different from the subject matter of the present application.

In denial of this reality, the Examiner argues that "the features upon which the appellant relies (i.e., the shell is non-expandable) are not recited in the pending claims." However, as noted

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above, the shell recited in the claims is inherently non-expandable and the shell is described in paragraph 27 of the application as being “inelastic, preferably plastic”. Thus, it is plainly incorrect for the Examiner to argue that this feature is not recited in the pending claims.

#### Balloon Attached to a Portion of the Stent

In an effort to find a basis for rejecting claim 3, which recites that Applicant’s “balloon” is “attached to a portion of the inner wall” of the stent, the Examiner argues that Figure 1 of the Dobak patents “display the balloon or chamber being attached to a portion” of the stent. This is untrue. The only balloon in the Dobak device of Figure 1 which can be considered comparable to the pumping balloon recited in Applicant’s claims is balloon 14 of Dobak which is used to provide the pumping action in Dobak’s device. The stent 20 of Dobak is **not** attached to pumping balloon 14 but rather is attached to the entirely separate balloon 16 which is disclosed in Dobak as functioning as a “housing”. Thus, it is completely inaccurate for the Examiner to argue that Figure 1 of Dobak shows a pumping balloon attached to a stent.

#### Stent Covered with Fabric

The Examiner argues that stent 20 of Dobak could be covered with a fabric. This is not true. It is essential to the structure of Dobak that the stent 20 be attached to a balloon which must necessarily be made of elastic material so that it can be expanded and contracted. This is disclosed, e.g., at column 5, lines 16-19 of Dobak ‘171 and column 6, lines 64-67 of Dobak ‘542. A fabric would not have the qualities necessary to function as a balloon.

#### Balloon Extending Around Full Circumference of Stent

As shown in Figure 1 of Dobak, pumping balloon 14 is separated from stent 20 by control chamber 26. Thus, pumping balloon 14 of Dobak cannot extend around the full circumference of the

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stent. The Examiner's argument to the contrary simply has no basis in Dobak. Thus, claims such as claim 13 and claims 23-27 distinguish from the Dobak patents for this additional reason.

Expansion of the Balloon Away From the Shell and Contraction Toward the Shell

Since, as noted above, the Dobak patents do not disclose a shell, they cannot possibly meet the terms of claims 23-27 which recite this feature. Furthermore, the Examiner's argument that this feature is met by the Dobak patents stands reality on its head. If the Examiner's erroneous position that balloon 18 of Dobak is a "shell" is accepted, it is plain that pumping balloon 14 moves toward balloon 18 when balloon 14 is expanded, not away from it as recited in the claims, and vice versa. Thus, these claims are patentable for this separate reason.

Balloon Does Not Extend Around the Full Circumference of the Stent

The argument made by the Examiner at lines 4-10 of page 12 that expansion of the pumping balloon of the present application such that it does not extend around the full circumference of the stent has not been disclosed as providing an advantage is badly off target. This feature as recited, e.g., in claims 14 and 32 is admitted by the Examiner to be absent from the Dobak patents. Indeed, the device of the Dobak patents is incapable of achieving such an expansion. It is not a proper basis for rejection of the claims for the Examiner to require disclosure of such an advantage. Rather, the device recited plainly has utility as a heart assist device and that is sufficient.

The Examiner's argument at page 12 that such a modification of the device of the Dobak patents would be obvious is baseless. Rather, it would be impossible for the device of the Dobak patents to be modified to function in this manner.



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### Bare Stent

This feature which is recited, e.g., in claims 12 and 15 is not specifically mentioned by the Examiner in the Examiner's Answer and is totally absent from the devices of Dobak. As shown in Figures 1 and 2, the stent 20 of Dobak is encased in balloon 16. Thus, it cannot have bare wires and cannot have the function of permitting blood flow between the bare wires of permitting blood flow into side vessels branching off from the aorta as disclosed in paragraph 29 of the present application.

### Placement of the Pressure Source Tube

All of the pressure delivery to the devices of Figures 1 and 2 of Dobak is accomplished with axial flow. In contrast, the device of the present invention uses a pressure delivery mechanism which delivers pressure transversely to the blood flow as illustrated in Figure 1 and described in paragraph 33. This feature is recited in claims 30-32 which recite that the shell has "a port in its wall to permit fluid flow into said balloon or chamber in a direction transversed to the direction of flow of blood through the vessel".

### Installation Procedures

Claims 20-22, 26 and 27 recite various procedures including sternotomy, aortotomy, thorascopically and forming an aperture in the wall of the aorta, which procedures are totally absent from the disclosures in the Dobak patents and which procedures could not be used with the devices of the Dobak patents. The Examiner, on page 14 of the Examiner's Answer, attempts to wish these patentable distinctions away by saying that such modifications to surgical procedures are well known. That is not the point. The point is that the Dobak patents disclose a device and procedures which are totally alien to the installation procedures recited in these claims.

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### Summary

The root cause of the fatal errors in the Examiner's rejections and in the Examiner's arguments is that there is no disclosure in the Dobak patents of the shell recited in all of the appealed claims. Because of this, the Examiner's attempts to force fit the additional features recited in the appealed claims into the Dobak patents does not and cannot work for the reasons stated in the appeal brief and in the present reply brief. Reversal of all of the rejections is respectfully requested.

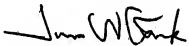
### Fees

The Commissioner is authorized to charge Orrick's Deposit Account No. **15-0665** for any fees required and credit any overpayments to said Deposit Account No. **15-0665**.

Respectfully submitted,

Orrick, Herrington & Sutcliffe, LLP

Dated: January 11, 2010

By:   
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